Embryo Donation in Iranian Legal System: A Critical Review

Zohreh Behjati-Ardakani 1, Mohammad Taghi Karoubi 2, Alireza Milanifar 1, Roudabeh Masrouri 1, Mohammad Mehdi Akhondi 1*

1- Reproductive Biotechnology Research Centre, Avicenna Research Institute, ACECR, Tehran, Iran
2- Department of law, Science and Culture University, Tehran, Iran

Abstract
Recent developments and newly-discovered methods for infertility treatment including in vitro fertilization and third party reproduction raise many questions and challenges with different ethical, legal, sociological and psychological dimensions. In Islamic countries, despite great developments in using this technology, the questions concerned with recognition of IVF methods and third party reproduction and legalization of this method are still the challenging ones. The approach of a few Shiite clerics to this issue has facilitated the legalisation of infertility treatment in Iran. The Iranian Parliament, with reference to Shiite clerics’ opinions (Fatwa), enacted the Act concerning Embryo Donation to Infertile Couples and its bylaw which can be considered as a successful example of legalization of third party reproduction in an Islamic country. The aforementioned Act permits embryo donation through artificial insemination from legally married couples to infertile couples. However, many of the legal aspects of this event are not specified in this Act and in many cases it added several uncertainties. This uncertainty, especially regarding the rights and duties of recipients and the child, causes important problems which generate more concerns. This article aimed to review the advantages and flaws of the Act. It is believed that the enactment of the aforementioned Act is an important step but an insufficient measure in this field. Important issues have been left unanswered and unclear in this Act which should be considered by legislators in any future revision of it.

Keywords: Embryo donation, Infertility treatment, Islamic law, Legislation, Third party reproduction.


Introduction

Scientific advances in the field of reproductive medicine over the past few decades have led to new method of infertility treatment including third party reproduction which provided new opportunities for infertile couples. However, the application of these methods has raised issues and questions which require the intervention of legislators for addressing them and consequently the relationship between the relevant parties should be redefined.

Third party reproduction through IVF can be used when one or both of the spouses is/are incapable of conceiving with their own embryo as a result of problems such as the lack of or defect in the sperm, oocytes or embryo, or having a genetically transmitted disease (1, 2). Sperm donation has been used for the treatment of male infertility for a century. However, egg donation for female infertility treatment was only employed after the invention of IVF (3). Embryo donation is also another, more recent, method of infertility treatment whereby IVF can be carried out using the embryo of third persons under special circumstances. This method involves controlled ovarian stimulation in female donor, harvesting the oocytes at appropriate time and fertil-
izing them with the sperm of a third party in an embryology lab. In this method, after the reproductive phase and at most 3 days after fertilization the embryo will be transferred to the infertile woman’s uterus. It is very rare to find a couple who have all of the disorders mentioned above; therefore, in most cases, the donation of one of the gametes would be enough to treat the couple (4).

Despite the undeniable benefits resulted from recent medical developments in treatment of infertility (such as IVF and third party reproduction), there remains several questions and challenges toward different moral, ethical, sociological and psychological dimensions which demand multidisciplinary studies and research (5). That is the reason why the countries which use a variety of fertilization methods have imposed various legal limitations on third party reproduction (6, 7). The use of IVF technology in Iran, an Islamic country which follows Shiite rules, dates back to 1988.

According to Article 4 of the Iranian Constitution, all laws and regulations must be consistent with Islamic principles. The Guardian Council supervises this conformity. The sources of Islamic law are as follows:

The Qur'an, the principal source of Islamic law, is believed by Muslims to be the absolute and final word revealed by God to Prophet Mohammad. It is therefore immutable and considered to be the first and most important source of legislation (8). To Muslim, it is the backbone of the fiqh, Islamic jurisprudence, the ultimate reference, and the whole of Sharia. Muslims treat the Qur'an not only as a source of law, but also as the main director of human life and any human rights regime must conform to those rights and duties, privileges and obligations enjoined upon believers in the Qur'anic verses (9). A second source of Islamic law is Sunna, which in Arabic means "way" or "custom". Sunna is defined by Sunni Muslims as the deeds, sayings and approvals of the Prophet Mohammad, while in the belief of Shi’a Muslims, Sunna means the deeds, sayings and approvals of Prophet Mohammad and his descendants (the twelve Imams) who were chosen by God to succeed the Prophet and to lead mankind in every aspect of life (10). To both schools of thought, Sunna as a second source of Islamic law consists of the Prophet’s sayings and deeds during his lifetime and his tacit approvals on different issues, both spiritual and temporal (11). Apart from the Qur’an and Sunna as primary sources of Islamic law, there are other juristic techniques such as Ijma- juristic consensus, Qiyas- analogical reasoning and Aql- human reason which are accepted as its secondary sources by both schools of thought.

When new questions arise that are needed to be answered from the Islamic point of view, Faqih (Islamic scholar) infer the answer from the sources mentioned above and gives his Fatwa (religious decree). Due to the importance and sensitivity of using third party reproduction techniques, Shiite clerics issued their Fatwa for the application of this innovative technology and provided the ground for enactment of new law in the field. Based on Shiite clerics' Fatwa, embryo donation as one of the methods of third party reproduction is only legitimate when the embryo is formed by the sperm and egg of a legally married couple (12). Therefore, through extensive studies in the field in terms of scientific, ethical and legal aspects and obtaining the Fatwa of Shiite clerics, the "Act concerning Embryo Donation to Infertile Couples" (hereinafter the Act 2005) was enacted by Iranian Parliament (13). This Act, containing five Articles and its bylaw which comprises ten Articles was drafted jointly by the Iranian Ministry of Health and Medical Education and the Ministry of Justice and passed by the Council of Ministers on 9 March 2005 (14).

Shiite clerics have different Fatwas about gamete donation. Many clerics consider fertilization as illegal if the sperm or egg is provided by an unmarried couple (15-17). Others believe that there is not any prohibition for use of this method in Islamic law and it is not considered as adultery; hence, they permit it (18-20). Unlike embryo donation, Iranian law is silent on gamete donation and no provision indicating prohibition or permission of this method exists in Iranian legal system.

Gamete donation is already done in some infertility clinics in Iran (based on some Fatwas which consider it legitimate). It seems that due to the importance of the issue and its personal and social consequences, careful surveillance in regulating this process is essential. It is necessary that the legislator proclaims its view regarding prohibition or permission of this method and if decides to permit it, legal terms and conditions of gamete donation and its consequences should be determined.

This article aimed to review the Act concerning Embryo Donation to Infertile Couples and its bylaw. Both the advantages and flaws of this legislation were examined.
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The ACT concerning embryo donation to infertile couples and its bylaw

The provisions of the Act and its bylaw can be categorized and studied under 4 titles including:
1. Legal conditions related to embryo formation and embryo transfer
2. Qualifications of recipients
3. Rights and obligations of recipients and the child born through embryo donation
4. Formalities and Civil Procedure.

1. Legal conditions related to embryo formation and embryo transfer

The competence of infertility clinics: The Ministry of Health and Medical Education has authorized all licensed infertility clinics to do embryo transfer procedure according to the Act. Moreover, the Ministry continuously monitors infertility clinics and issues certification for health care services.

The observance of religious criteria: As mentioned in the Act, the practice needs to comply with religious criteria for both embryo formation and embryo transfer stages. Shiite clerics state that legally married couples who did not have forbidden sex and abide by the Islamic law are permitted to donate their qualified embryos. Forbidden prerequisites are specifically defined as forbidden gaze or physical contact with a non-mahram person or ejaculation through masturbation. Therefore, under religious reservations as mentioned above, the formation of embryo through the egg and sperm of the donors is permitted. According to Shiite clerics view, forbidden gaze and physical contact should also be avoided during embryo transfer.

IVF embryo formation of legally married couples: There are different methods for artificial insemination; however, in vitro fertilization as an alternative for embryo formation and its transfer to the uterus is the one approved by the Act, since Shiite clerics have recognized it permissible. Meanwhile, it has been specified in the Act that there should be a marital relationship between egg and sperm owners. Hence, the general trend in infertility clinics is that they are permitted to use the excess embryos remaining from in vitro fertilization treatments of the infertile couples. For donating the remaining embryos to infertile applicants, a written consent form should be signed by the donors.

In addition to the written consent of donors which has been specified as the main requirement in the Act (Article 2), the bylaw accentuates the importance of issues like physical and mental health of donors, non-addiction to alcohol and drug and non-suffering from AIDS or Hepatitis which require the attentive consideration of infertility clinics at the early stages of embryo donation (Article 2). The bylaw also stresses that donor and applicant information will be registered on a confidential basis (Article 3).

2. Qualifications of recipients

According to the Act and its bylaw, embryo recipients should meet the following criteria: Legally married couples are just eligible to request for receiving a donated embryo. A single woman or a widow is not permitted to apply for this method.

- If applicants are recognized as infertile based on valid medical testimony (one or both of partners), they would be eligible for application. All licensed infertility clinics are authorized to issue the certificate after essential considerations.
- The court should endorse moral competence of the couples.
- The sanity of couples must be verified.
- Couples must not be suffering from any incurable ailments and Hepatitis and AIDS. Medical tests should be performed on the couples.
- Neither the wife nor the husband must be addicted to narcotics.
- Couples must be citizens of Islamic Republic of Iran.
- Couples should enjoy physical and mental health.

3. Rights and obligations of recipients and the child born through embryo donation

The most controversial section of the Act is the clarification of the relationship between embryo recipient and the child born through embryo donation. Article 3 of the Act states that "All parental rights, duties and responsibilities such as guardianship, respect, protection and alimony in biologic parent-child relationship should be observed in parent-IVF child relationship as well". The Article is similar to Protection of Orphan Children Act 1974, Article 11. Accordingly, the legislator has complied with the traditional view of the Shiite clerics who consider the egg and sperm owners as the biologic parent of the child. According to Islamic rulings, kinship would be ascertained through three ways: consanguinity (relationship by birth in the same family), marriage, and fostering (relationship by breast-feeding in infancy). Marrying close relatives (parents, siblings, offspring, aunts, uncles, grandparents, and foster brothers or sisters) is unlawful in Islam. In Islamic law, inher-
The strengths and flaws of the ACT and its bylaw

Embryo donation to infertile couples was legalized in Iran because of famous Shiite clerics’ opinions (Fatwa), though there are a variety of opinions among Shiite clerics in this regard. That is the reason why some methods of IVF have been accepted in Iran while they are not legalized in some other countries, including many other Islamic countries (22). The aforementioned opinions can contribute to the expansion and development of fertilization technology in Islamic countries and can play a significant role in saving many families (23).

This Act, despite many advantages, contains some ambiguity and creates certain problems which need to be addressed. However, before addressing those concerns, the advantages of the Act will be reviewed in brief:

1. Advantages
- The Act and its bylaw was an important step towards addressing the psychological and social problems of infertile couples who seek the use of IVF technology. The legalization of this treatment method prevents many cases of divorce and plays an important role in saving many families which would otherwise fall apart due to the infertility of one or both of the partners. The right to have a family is one of the important rights in Islam, as in human rights conventions (24).
- One of the highlights of the Article 2 of the Act and the second chapter of its bylaw is the evaluation of the couples’ physical and mental health and the requirement of absence of any incurable ailments in couples receiving an embryo. Obviously, embryo donation requires the use of donating couples’ healthy gametes (sperm and/or eggs). Since these cells carry the genetic codes of the donor, any genetic ailment could be passed on to the child. Moreover, in this process, the recipients could also be placed in danger (24).
- Third party reproduction (through embryo donation) can only be used if couples seek this method as a treatment of infertility. Article 1 of the Act authorizes all licensed infertility treatment clinics to carry out tests to prove the infertility of the male or female partner before using the embryo donation methods.
- The Act and its bylaw create an area for legal and jurisprudential discussions over the concepts such as parentage, inheritance, guardianship of the child, etc. Such discussions can contribute to the clarification of the rights and duties of recipients, the new born child and their relations with donors.
- Although there is no mention of the confidentiality of the donors’ and recipients’ identities in the Act, the need for confidentiality of such information and documents has been recognized in the bylaw. Furthermore, the obligation for classifying the above information as "top secret" eliminates any concerns about the disclosure of donors’ identity and/or any issues regarding custody, guardianship or donors’ rights about the inheritance of the child (25).
- The emphasis of the bylaw on the "voluntary" and "free of charge" nature of embryo donation prevents any commercial intention and/or sale of an embryo. However, if such provision had been mentioned explicitly in the Act, it could have been an advantage.
- Article 4 of the Act states that assessment of the eligibility of couples seeking embryo donation will be carried out in the Family Court and without having to wait or go through the formalities of
the law of Civil Procedure. Given the long waiting lists in the family courts as a result of the formalities of the law, this provision accelerates the process of treatment. This article also confirms the right of couples to appeal against the decision of the Family Court in a higher court of appeal.

2. Ambiguity of the Act and its bylaw

Despite the aforementioned benefits of the Act concerning Embryo Donation to Infertile Couples and its bylaw, one should note that there are serious ambiguities and flaws in these provisions which create difficulties and have important implications. A good piece of legislation should clarify, as far as possible, any ambiguity and therefore prevent the possibility of any misuses. One would expect that a good bylaw would explain and interpret the provisions of law in order to facilitate better implementation. Some of the ambiguities and flaws of the Act concerning Embryo Donation to Infertile Couples and its bylaw are addressed in brief as follows:

- According to Article 1, all licensed infertility treatment clinics are authorized to transfer an embryo resulting from in vitro fertilization only after the tests demonstrate the infertility of the female or male partner (or both of them). Since the evaluation and confirmation of infertility is not always an easy task, the need is felt for a consistent directive that calls for confirmation of the existence or lack of sperm and/or eggs in couples who seek embryo donation and also of the ability of the female partner to receive and keep an embryo. Leaving this matter in the hands of various licensed infertility treatment clinics can create many problems in terms of consistency.

- According to Article 1 of the Act, embryo donation is used as a treatment for couples whose infertility has been confirmed after marriage and medical treatment. There is no mention in either the Act or its bylaw whether married couples who have one child but then rendered infertile could profit from this treatment. As there is not any express prohibition in this regard it can be considered as allowed. But as different infertility treatment clinics might have different directives in this regard it needs to be dealt with in any future amendment of the Act to avoid inconsistent practices.

- There is no mention in either the Act or its bylaw of the possibility of the use of this method for couples who may have gamete or embryo, but suffer from or carry a disease or have a genetic disorder which could be transferred to the child. This may prevent the use of this method for a group of people who are in great need of it (26).

- Article 1 uses the expression "legally married couples" about the recipients. It is unclear whether this expression includes only formally registered and permanent marriages or temporary marriages can also be included. If one aims for a literal interpretation of this expression, then one needs to include both types of marriages under the scope of this law. Logically, on the other hand, this expression should only aim to support permanent marriages; however, licensed clinics need a clear legal provision to act upon it. In this vein, an important question remains; if the literal interpretation is accepted by Parliament or by family courts which act upon it, what would be the status of the child? Moreover, if legal marriage is a necessary requirement of the applicants, what would happen if the couple in question divorce before the transfer of the embryo? Can the couple in question revoke their joint request and consent while the treatment is in progress? In revocable divorce (Reje’i divorce - a kind of Islamic divorce in which couples have the right to revoke the divorce during a certain waiting period (Iddah) after which the divorce will be irrevocable), according to clerical opinions, couples would be considered “married” during the waiting period (Iddah); so the treatment can be carried out but does it really serve the best interests of the child? Moreover, the Act is silent about the question of the death of one of the partners during the treatment and this adds to the ambiguity (27).

- According to Article 2(5) of the Act, one of the requirements for receiving an embryo is freedom from addiction to narcotics. Though the Act applies this requirement only to the recipients, the bylaw extends it to donors as well. But as a substantive requirement for donors, it should have been mentioned in the Act itself. Moreover, the evaluation and confirmation of freedom from addiction to some psychedelic substances (as another requirement for recipients and donors mentioned in the bylaw) seems impractical. The mention of "psychedelic substances" in general terms would only add to the ambiguity and practical problems. In the General Policies of the Islamic Republic of Iran on Combating the Drugs (2006), the use of any narcotic or psychedelic substance has been considered as a crime and in the draft Amendment to the Law on Combating the Drugs
in conformity with the aforementioned General Policies, "narcotic substances" were mentioned as a general term and "psychedelic substances" were considered as an instance below it.

- According to the Act concerning Embryo Donation to Infertile Couples, recipients shouldn't be suffering from any incurable diseases. In the by-law, this condition has also been expanded to donors and has been clarified by using examples such as HIV and Hepatitis. These examples are not exclusive and the aim of mentioning them is simply to point out the best known incurable ailments. However, since there is no accepted definition of "incurable diseases" and nor are there any accepted lists of such ailments in any medical field, such a general approach may unfairly deprive certain groups of people, which is contrary to the purpose of this Act. As there is no accepted definition of "incurable diseases" in Iranian medical or legal literature, this could lead to different interpretations; for instance, Hepatitis has been mentioned as an incurable disease in the bylaw, while there is no explanation in either the Act or its bylaw which distinguishes between different types of Hepatitis, its active or non-active status, the possibility or impossibility of its transfer to the child, etc. Moreover, the notion of "incurable", given the rapid developments of medical science, can differ from day-to-day (28).

- The necessity of having a consistent directive for evaluation of the "normal physical and mental health and suitable intelligence quotient" of donors and recipients is undeniable. It seems that, on the one hand, the absence of any incurable diseases has been mentioned as the necessary requirement for both donors and recipients while, on the other hand, great emphasis has been placed on the couples' normal health. There was no need for these two contradictory provisions and it seems that enjoying normal health suffices. Moreover, infertility should be excluded from the scope of this provision; otherwise none of the candidates enjoys normal health! Perhaps stating all of the criteria for "normal health" by the Act is the best way to overcome this conflict.

- The requirements for couples to receive an embryo have been mentioned in the Act and the requirements for donors have been set out in the bylaw; however, according to Article 2 of the Act and Article 2 of the bylaw, evaluation and confirmation of these requirements have been assigned to two different entities (Family Court and licensed clinics). It seems more practical for the assessment of these requirements to be left to licensed clinics and then confirmed by family courts.

- Nowadays, embryo donation is used for couples when both male and female partners are in need of treatment. If only one of the partners lacks the gamete, the gamete donation method will be used. However, as the Iranian legal system has not made any distinction between these two cases and there is no provision in regard to gamete donation, embryo donation is the only legal choice for treatment of all kinds of incurable infertility. However, in view of the possibility of using IVF methods in Iran and as some Shiite clerics allow donation and receiving of gametes, it may be a more practical method with less cost and formality. In fact, since in gamete donation one of the partners has a contribution in making the embryo (one of the partners' gamete would be used together with the donated gamete), recipients might have stronger emotional bonds with the child.

- According to a traditional opinion in Islamic jurisprudence, the child belongs to semen owners and the biological relation between the child and those who have conceived the embryo determines legal parentage (provided that the biological parents can be considered as "legally married" ones). According to this opinion, the embryo that is created with the use of IVF methods can easily be recognized as the donors’ child. Since in this method all of the necessary factors for confirming parentage, such as legal marriage, the birth of the child and other valid evidence exist, traditional clerics believe that the donors are considered as the child’s parents. Article 3 of the Act states that "All parental rights, duties and responsibilities such as guardianship, respect, protection and alimony in biologic parent-child relationship should be observed in parent-IVF child relationship as well". It seems that this Article has followed the traditional opinion and in conformity with Article 11 of the "Act for Protection of Orphan Children" (1974) has not recognized any inheritance relationship between the new born and recipients (29). In other words, the Act imposes parental obligations on the recipients but doesn’t recognize them as the child’s parent and has not done anything to support their rights. It should be noted that considering the best interest of the child, family and society as a whole, the aforementioned approach can be subjected to criticism. Moreover,
obliging donors to accept the new born as their child and its legal implications is contrary to their intention. It seems suitable that the inheritance relationship should be recognized between the new born and the recipients who intend to have the child in their family and have expressed their consent in this regard.

Conclusion
The enactment of the Act concerning Embryo Donation to Infertile Couples and its bylaw was an important step for resolving legal problems of infertile couples who can be assisted by the use of IVF methods. The aforementioned Act can be considered as an important development in Islamic law. Undoubtedly, one of the most important reasons for enactment of this Act was confirmation of the legitimacy of infertility treatment (through the use of third party reproduction) by many Shiite clerics. This Act, despite many advantages, contains some ambiguity and creates certain practical problems. One of the most important of these flaws is the lack of recognition of legal parentage relation between the child and recipients. This traditional approach, on the one hand, unfairly deprives recipients and the child of some of their rights and on the other hand, imposes a constant legal relationship between the child and the donors against their intention. In fact, according to the theory of "Intention and Waiver" as both parties intend the donors would waive" as both parties intend the donors would

Conflict of Interest
The authors declare no conflict of interest.

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